Hinds Circuit Page 1 of 2

Case 3:14-cv-00730-TSL-RHW Document 3 Filed 09/18/14 Page 1 of 19

Mississippi Electronic Courts Hinds County Circuit Court (Hinds Circuit Court - Jackson) CIVIL DOCKET FOR CASE #: 25CI1:14-cv-00541-JAW

SIMPSON v. MERCK & CO., INC. et al

Assigned to: Jeff Weill, Sr

Date Filed: 08/20/2014

Jury Demand: None

Nature of Suit: 183 Products Liability

Jurisdiction: General

Plaintiff

JUDITH C SIMPSON

represented by Robert G Germany

410 South President St. JACKSON, MS 39201

601-948-6200 Fax: 601-948-6187

Email: rgg@pgrwlaw.com
ATTORNEY TO BE NOTICED

V.

Defendant

MERCK & CO., INC.

Defendant

MERCK SHARP & DOHME, CORP.

Date Filed	#	Docket Text
08/20/2014	2	COMPLAINT against MERCK & CO., INC., MERCK SHARP & DOHME, CORP., filed by JUDITH C SIMPSON. (Attachments: # 1 Civil Cover Sheet) (SH) (Entered: 08/20/2014)
08/20/2014	<u>3</u>	SUMMONS Issued to MERCK & CO., INC RET TO ATTY. (SH) (Entered: 08/20/2014)
08/20/2014	4	SUMMONS Issued to MERCK SHARP & DOHME, CORP RET TO ATTY. (SH) (Entered: 08/20/2014)

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		Criteria:	JAW
Billable Pages:	1	Cost:	0.20

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FILED

IN THE CIRCUIT COURT OF HINDS COUNTY, MISSISSIPPI AUG 20 2014 FIRST JUDICIAL DISTRICT

BARBARA DUNN, CIRCUIT CLERK

PLAINTIFF

JUDITH C. SIMPSON

V.

CIVIL ACTION NO. 14 - 54

JURY TRIAL DEMANDED

MERCK & CO., INC. and MERCK SHARP & DOHME, CORP.

DEFENDANTS

COMPLAINT

Plaintiff, JUDITH C. SIMPSON residing at 121 Hillcroft Dr., Jackson, Mississippi, by and through her undersigned attorney, hereby sues the defendants, MERCK & CO., INC. and MERCK SHARP & DOHME, CORP. (hereinafter referred to as "Defendants"), which have their principal place of business at One Merck Drive, P.O. Box 100, Whitehouse Station, New Jersey 08889-0100, and alleges as follows:

I. Background.

- 1. This is an action for damages suffered by Plaintiff as a direct and proximate result of the Defendants' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, and/or sale of the pharmaceutical product known as Fosamax (hereinafter referred to as "Fosamax" or "the subject product").
- 2. At all times material hereto, Fosamax was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants.

II. Parties.

3. Plaintiff is a resident of Jackson, Mississippi.

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4. Judith C. Simpson was prescribed and took Fosamax (Alendronate) for at least eleven years prior to August 25, 2011.

- 5. The Defendants are New Jersey corporations, which have their principal place of business in Whitehouse, New Jersey.
- 6. At all times material hereto, the Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Fosamax.

III. Substantive Allegations.

- 7. Defendants knew of the significant risk of dental and oral complications and stress femur fractures caused by ingestion of Fosamax, but Defendants did not adequately and sufficiently warn consumers, including Judith C. Simpson, or the medical community, of such risks.
- 8. Consumers, including Judith C. Simpson, who have used Fosamax for treatment of osteoporosis, have several alternative safer products available to treat this condition.
- 9. As a result of Defendants' actions, Judith C. Simpson and her prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Judith C. Simpson had been exposed to the risks identified in this complaint, and that those risks were the direct and proximate result of Defendants' acts, omissions, and misrepresentations.
- 10. As a direct result, Judith C. Simpson was prescribed and ingested Fosamax and has been permanently and severely injured. Judith C. Simpson requires and will require ongoing medical care and treatment.

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a. Defendants' Development and Marketing of Fosamax.

- 11. Alendronate sodium and alendronate sodium/choleacalciferol were designed, formulated, patented, marketed, sold and distributed by the Defendants under the brand names "Fosamax" and "Fosamax Plus D."
- 12. At all relevant times Defendants were responsible for, or involved in, designing, manufacturing, marketing, advertising, distributing, and selling Fosamax.
- 13. In September 1996, Fosamax was approved for marketing and sale in the treatment of osteoporosis and Paget's disease.
- 14. Fosamax falls within a class of drugs known as bisphosphonates. Bisphosphonates are used for treating bone conditions such as osteoporosis and Paget's disease.
- 15. There are two classes of bisphosphonates: the N-containing (nitrogenous) and non-N-containing (non-nitrogenous) bisphosphonates. The nitrogenous bisphosphonates include the following: pamidronate (Aredia); ibandronate (Bondronat); and alendronate (Fosamax). The non-nitrogenous bisphosphonates include the following: etridonate (Didronel); clodronate (Bonefos and Loron); and tiludronate (Skelid). Alendronate, like others, contains a nitrogen atom, whereas etridonate, clodronate, and tiludronate do not. The PDR for Fosamax confirms that the molecule contains a nitrogen atom.
- 16. While Fosamax might help bone density in some people, experts now say its benefits for preventing bone fracture are minimal, and if taken over long periods of time, the drug can make bones more brittle and increase the risk of fracture.
- 17. Studies have also reported on the occurrence of stress fractures in the femoral shaft in patients receiving alendronate therapy. There has been a long standing concern among experts in the medical community that bisphosphonate changes to bone metabolism result in

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poor bone quality and impaired microdamage repair resulting in non- traumatic femoral shaft fractures. Despite this knowledge, Defendants failed to implement further studies and failed to warn patients and the medical community on the risks of femur fractures relative to the prolonged usage of Fosamax. Rather than evaluating and verifying the safety of Fosamax with respect to femur fractures, Defendants continued and continue to defend and aggressively market Fosamax, while downplaying any unfavorable findings and overstating its benefits.

- 18. Fosamax remains in the body for years after ingestion.
- 19. Rather than warn patients and the medical community, and despite knowledge by Defendants of increased risk of femur fractures in patients using Fosamax, Defendants continued and continue to defend and aggressively market Fosamax, while downplaying any unfavorable findings and overstating its benefits.
- 20. Fosamax is the world's top-selling bisphosphonate and Defendants' second-best selling drug, with more than 22 million prescriptions in 2005 amounting to \$3.2 billion in sales.
 - b. Judith C. Simpson's Use of Fosamax.
- 21. Judith C. Simpson, was prescribed and took Fosamax (Alendronate) for over eleven years prior to August 25, 2011.
 - 22. Judith C. Simpson used Fosamax as prescribed and in a foreseeable manner.
- 23. Judith C. Simpson used Fosamax that had been provided to her in a condition that was substantially the same as the condition in which it was manufactured and sold.
- 24. As a direct and proximate result of using Fosamax, on August 25, 2011, Judith C. Simpson suffered a fracture of her femur.

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- 25. Judith C. Simpson, as a direct and proximate result of using Fosamax, suffered severe mental and physical pain and suffering and has sustained permanent injuries and emotional distress.
- 26. Judith C. Simpson would not have used Fosamax had Defendants properly disclosed the risks associated with the drug.

IV. Products Liability - Failure to Warn.

- 27. The foregoing paragraphs of this Complaint are realleged and incorporated by reference.
- 28. Defendants designed, tested, manufactured, marketed, sold and/or distributed Fosamax. As such, it had a duty to warn the using public, including Judith C. Simpson, of the health risks associated with using the subject product.
- 29. The subject product was under the exclusive control of Defendants and was unaccompanied by appropriate warnings regarding the health risks associated with its use, including but not limited to osteonecrosis of the jaw and stress femur fractures. The warnings given did not accurately reflect the risk, incidence, symptoms, scope or severity of such injury to the consumer. The promotional activities of Defendants further diluted or minimized the warnings given with the product.
- 30. The subject product was defective and unreasonably dangerous when it left the possession of the Defendants in that it contained warnings insufficient to alert Judith C. Simpson to the dangerous risks and reactions associated with it, including, but not limited to stress femur fractures. Even though Defendants knew or should have known of the risks and reactions associated with the subject product, they still failed to provide warnings that accurately reflected the signs, symptoms, incidence, scope, or severity of these risks.

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31. Judith C. Simpson used the subject product for its intended purpose, i.e. for the prevention or treatment of osteoporosis.

- 32. Judith C. Simpson could not have discovered any defect in the subject product through the exercise of reasonable care.
- 33. Defendants, as a manufacturer of pharmaceutical drugs, are held to the level of knowledge of an expert in the field, and further, Defendants had knowledge of the dangerous risks and side effects of the subject product.
- 34. Judith C. Simpson did not have the same knowledge as Defendants and no adequate warning was communicated to her.
- 35. Defendants had a continuing duty to warn consumers, including Judith C. Simpson, of the dangers associated with the subject product. By negligently and/or wantonly failing to adequately warn of the dangers of use of the subject product, Defendants breached their duty.
- 36. Although Defendants knew of the defective nature of the subject product, they continued to design, manufacture, market, and sell it without providing accurate, adequate, and complete warnings concerning its use so as to maximize sales and profits at the expense of the public health and safety, in knowing, conscious, and deliberate disregard for the foreseeable harm caused by the subject product.
- 37. As a direct and proximate result of the Defendants' failure to adequately warn or other wrongdoing and actions of Defendants described herein, Judith C. Simpson has sustained serious and permanent injuries, and will continue to suffer injury, harm, and economic loss.

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WHEREFORE, Judith C. Simpson demands judgment against Defendants, jointly and severally, for compensatory and punitive damages, together with interest, costs of suit, attorney's fees and all such other relief as the Court deems proper.

V. Products Liability – Defective Design.

- 38. The foregoing paragraphs of this Complaint are realleged and incorporated by reference.
- 39. Defendants are the manufacturer, seller, distributor, marketer, and/or supplier of the subject product, which is defective and unreasonably dangerous to consumers.
- 40. The subject product was designed, manufactured, sold, distributed, supplied, marketed, and/or promoted by Defendants, and was expected to reach and did reach consumers, including Judith C. Simpson, without substantial change in the condition in which it was manufactured and sold by Defendants.
- 41. The subject product was defective in its design and was unreasonably dangerous in that its foreseeable risks exceeded the benefits associated with its design or formulation.
- 42. Although Defendants actually knew of the defective nature of the subject product, they continued to design, manufacture, market, and sell it so as to maximize sales and profits at the expense of the public health and safety, in knowing, conscious and deliberate disregard of the foreseeable harm caused by the subject product.
- 43. As a direct and proximate result of the design defects of the subject product, Judith C. Simpson has sustained serious and permanent injuries, and will continue to suffer, injury, harm, and economic loss.

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WHEREFORE, Judith C. Simpson demands judgment against Defendants, jointly and severally, for compensatory and punitive damages, together with interest, costs of suit, attorney's fees and all such other relief as the Court deems proper.

VI. Products Liability – Breach of Implied Warranty.

- 44. The foregoing paragraphs of this Complaint are realleged and incorporated by reference.
- 45. Defendants manufactured, marketed, sold, and distributed the subject product specifically for the prevention of osteoporosis.
- 46. At the time Defendants marketed, sold, and distributed the subject product for use by Judith C. Simpson, Defendants knew of the purpose for which it was intended and impliedly warranted the subject product to be of merchantable quality and safe and fit for such use.
- 47. Contrary to such implied warranty, the subject product was not of merchantable quality and was not safe or fit for its intended use.
- 48. Judith C. Simpson purchased and used the subject product for the prevention of osteoporosis.
- 49. Judith C. Simpson reasonably relied on the skill, superior knowledge, and judgment of Defendants as to whether the subject product was of merchantable quality and safe and fit for its intended use.
- 50. Due to Defendants' wrongful conduct as alleged herein, Judith C. Simpson could not have known about the risks and side effects associated with the subject product until after Judith C. Simpson used it.

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51. As a direct and proximate result of Defendants' breach of implied warranty, Judith C. Simpson has sustained serious and permanent injuries, and will continue to suffer, injury, harm, and economic loss.

WHEREFORE, Judith C. Simpson demands judgment against the Defendants, jointly and severally, for compensatory and punitive damages, together with interest, costs of suit, attorney's fees and all such other relief as the Court deems proper.

VII. Breach of Express Warranty.

- 52. The foregoing paragraphs of this Complaint are re-alleged and incorporated by reference.
- 53. Defendants expressly represented to Judith C. Simpson, other consumers and the medical community that Fosamax was safe and fit for its intended purposes, that it was of merchantable quality, that it did not produce any dangerous side effects, and that it was adequately tested.
- 54. Fosamax did not conform to Defendants' express representation because it is not safe, has numerous and serious side effects, and causes severe and permanent injuries.
- 55. At all relevant times Fosamax did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.
- 56. Judith C. Simpson, other consumers and the medical community relied upon Defendants' express warranties.
- 57. As a direct and proximate result of Defendants' express warranties of the subject product, Judith C. Simpson has sustained serious and permanent injuries, and will continue to suffer, injury, harm, and economic loss.

WHEREFORE, Judith C. Simpson demands judgment against Defendants, jointly and severally, for compensatory and punitive damages, together with interest, costs of suit, attorney's fees and all such other relief as the Court deems proper.

VII. Punitive Damages.

- 58. The foregoing paragraphs of this Complaint are realleged and incorporated by reference.
- 59. Although Defendants knew or recklessly disregarded the fact that the subject product causes debilitating and potentially lethal side effects, Defendants continued to market the subject product to consumers, including Judith C. Simpson, without disclosing these side effects.
- 60. Defendants knew of the subject product's defective nature, as set forth herein, but continued to design, manufacture, market, and sell it so as to maximize sales and profits at the expense of the health and safety of the public, including Judith C. Simpson, in conscious and/or negligent disregard of the foreseeable harm caused by the subject product.
- 61. Defendants intentionally concealed or recklessly failed to disclose to the public, including Judith C. Simpson, the potentially life-threatening side effects of the subject product to ensure their continued and increased sales. This intentional and/or reckless failure to disclose information deprived Judith C. Simpson of the information necessary for her to weigh the true risks of using the subject product against the benefits.
- 62. Defendants' aforementioned conduct was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers such as Judith C. Simpson, thereby entitling Judith C. Simpson to punitive damages in an amount appropriate to punish Defendants and it from similar conduct in the future.

WHEREFORE, Judith C. Simpson demands judgment against Defendants, jointly and severally, for compensatory and punitive damages, together with interest, costs of suit, attorney's fees and all such other relief as the Court deems proper.

IX. Fraudulent Concealment.

- 63. The foregoing paragraphs of this Complaint are realleged and incorporated by reference.
- 64. Defendants, from the time that Fosamax (Alendronate) was first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed, and up to the present, willfully deceived Judith C. Simpson by concealing from Judith C. Simpson, Judith C. Simpson's health care providers and the general public, the true facts concerning the Fosamax (Alendronate), which the Defendants had a duty to disclose. Although Defendants knew or recklessly disregarded the fact that the subject product causes debilitating side effects, Defendants continued to market the subject product to consumers, including Judith C. Simpson, without disclosing these side effects.
- 65. At all times relevant hereto, Defendants, and each of them, conducted a sales and marketing campaign to promote the sale of the Fosamax (Alendronate) and willfully deceived Judith C. Simpson, Judith C. Simpson's physicians and the general public as to the health risks and consequences of the use of the Fosamax (Alendronate). Defendants, and each of them, were aware of the foregoing, and that the Fosamax (Alendronate) was not safe, fit, and effective for human consumption. Furthermore, Defendants were aware that the use of the Fosamax (Alendronate) was hazardous to health, and that the Fosamax (Alendronate) has a significant propensity to cause serious injuries to users including, but not limited to, the injuries suffered by Judith C. Simpson as described herein.

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66. Defendants intentionally concealed and suppressed the true facts concerning the Fosamax (Alendronate) with the intent to defraud Judith C. Simpson, in that Defendants knew that her physicians would not have prescribed Fosamax (Alendronate) and Judith C. Simpson would not have used the Fosamax (Alendronate) if Judith C. Simpson had known the true facts concerning the dangers of the Fosamax (Alendronate). As a result, Judith C. Simpson and her physicians justifiably relied upon the facts as misrepresented by Defendants concerning Fosamax (Alendronate).

67. As a result of the foregoing fraudulent and deceitful conduct by Defendants, and each of them, Judith C. Simpson suffered injuries and damages as described above.

WHEREFORE, Judith C. Simpson demands judgment against Defendants, jointly and severally, for compensatory and punitive damages, together with interest, costs of suit, attorney's fees and all such other relief as the Court deems proper.

WHEREFORE, Judith C. Simpson respectfully prays of this Court and demands of Defendants as follows:

- a. That Judith C. Simpson be granted and recover actual damages incidental to her purchase and use of Fosamax in an amount to be determined at trial;
- b. That Judith C. Simpson be granted and recover punitive damages;
- c. That Plaintiff be granted pre-judgment and post-judgment interest;
- d. That Plaintiff be granted reasonable attorney's fees and costs as provided by law; and
- e. That the costs of this action be taxed to Defendants;

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JURY TRIAL DEMANDED

The Plaintiff demands a trial by jury on all issues

Dated: August <u>20</u>, 2014.

By:

Robert G. Germany, MSB #4800

Httman, Germany, Roberts & Welsh, L.L.P.

10 South President Street (39201)

Post Office Box 22985 Jackson, MS 39225-2985

Telephone: 601-948-6200 Facsimile: 601-948-6187

Attorney for Plaintiff

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Plaintiff - Party(ies) Initially Bringing S	uit Should Be Entered First - En	ter Additional Plaintiffs on Separate Form	
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Nature of Suit (Place an "X" in one box		Children/Minors - Non-Domestic	Real Property
Domestic Relations	Business/Commercial	Adoption - Contested	Adverse Possession
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Contempt	Debt Collection	Removal of Minority	Eviction
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Paternity	Probate	Post Conviction Relief/Prisoner	Other
Property Division	Accounting (Probate)	Other	Torts
Separate Maintenance	Birth Certificate Correction	Contract	Bad Faith
Termination of Parental Rights	Commitment	Breach of Contract	Fraud
UIFSA (eff 7/1/97; formerly URESA)	Conservatorship	Installment Contract	Loss of Consortium
Other	Guardianship	Insurance	Malpractice - Legal
Appeals	Heirship	Specific Performance	Malpractice - Medical
Administrative Agency	intestate Estate	Other	Mass Tort
County Court	Minor's Settlement	Statutes/Rules	Negligence - General
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MS Dept Employment Security	Testate Estate	Declaratory Judgment	Subrogation
Worker's Compensation	Will Contest	Injunction or Restraining Order	Wrongful Death
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IN THE <u>CI</u>	RCUIT	COURT OF HINDS	County, Mississippi
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DEFENDANTS IN REFERENCED CAUSE - Page 1 of ___ Defendants Pages IN ADDITION TO DEFENDANT SHOWN ON CIVIL CASE FILING FORM COVER SHEET

Defendant #2:								
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IN THE CIRCUIT COURT OF HINDS COUNTY, MISSISSIPPI FIRST JUDICIAL DISTRICT

JUDITH C. SIMPSON

PLAINTIFF

V.

CIVIL ACTION NO. /4

JURY TRIAL DEMANDED

MERCK & CO., INC. and MERCK SHARP & DOHME, CORP.

DEFENDANTS

SUMMONS

You are Hereby Commanded to Summons:

Merck & Co., Inc. One Merck Drive P. O. Box 100 Whitehouse Station, New Jersey 08889-0100

NOTICE TO DEFENDANT

The Complaint which is attached to this Summons is important and you must take immediate action to protect your rights by filing your Answer as provided by law and/or the Mississippi Rules of Civil Procedure.

This Answer must be filed as provided by law and/or the Mississippi Rules of Civil Procedure within 30 days of the date you are served or a Judgment by Default may be entered against and for the money or other things demanded in the Complaint.

DATED this the ______ day of August, 2014.

BARBARA DUNN, CIRCUIT CL

RV:

BARBARA DUNN, CIRCUIT CLERK HINDS COUNTY, FIRST DISTRICT

P. O. BOX 327

JACKSON, MS 39205

ROBERT G. GERMANY (MSB# 4800)
PITTMAN, GERMANY, ROBERTS & WELSH, L.L.P.
410 South President Street (39201)

Post Office Box 22985

Jackson, Mississippi 39225-2985

Telephone: 601-948-6200 Facsimile: 601-948-6187

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IN THE CIRCUIT COURT OF HINDS COUNTY, MISSISSIPPI FIRST JUDICIAL DISTRICT

JUDITH C. SIMPSON

PLAINTIFF

V.

CIVIL ACTION NO. 14-57

JURY TRIAL DEMANDED

MERCK & CO., INC. and MERCK SHARP & DOHME, CORP.

DEFENDANTS

SUMMONS

You are Hereby Commanded to Summons:

Merck Sharp & Dohme, Corp. One Merck Drive P. O. Box 100 Whitehouse Station, New Jersey 08889-0100

NOTICE TO DEFENDANT

The Complaint which is attached to this Summons is important and you must take immediate action to protect your rights by filing your Answer as provided by law and/or the Mississippi Rules of Civil Procedure.

This Answer must be filed as provided by law and/or the Mississippi Rules of Civil Procedure within 30 days of the date you are served or a Judgment by Default may be entered again. For the money or other things demanded in the Complaint.

DATED this the 20 day of August, 2014.

BARBARA DUNN, CIRCUI

 \mathbf{RV}

ROBERT G. GERMANY (MSB# 4800) PITTMAN, GERMANY, ROBERTS & WELSH, L.L.P. 410 South President Street (39201) Post Office Box 22985

Jackson, Mississippi 39225-2985

Telephone: 601-948-6200 Facsimile: 601-948-6187

BARBARA DUNN, CIRCUIT CLERK HINDS COUNTY, FIRST DISTRICT

P. O. BOX 327

JACKSON, MS 39205